UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

LAFAYETTE DIVISION

OUITA CORLEY	CIVIL ACTION NO. 13-2571
VERSUS	JUDGE DOHERTY
STRYKER ORTHOPAEDICS, A DIVISION OF STRYKER CORP. AND STRYKER SALES CORP.	MAGISTRATE JUDGE HANNA

MEMORANDUM RULING

Pending before this Court is a Report and Recommendation issued by the magistrate judge, in which the magistrate judge recommends the "Motion to Dismiss for Failure to State a Claim in Plaintiff's Third Amended Complaint" [Doc. 27] be granted in part and denied in part, and certain claims of the plaintiff be dismissed. Defendants Stryker Corporation and Stryker Sales Corporation[1] filed an Objection to the Report and Recommendation [Doc. 32]. After this Court's *de novo* review of the issues presented, this Court ADOPTS the findings of the magistrate judge and concludes certain claims of the plaintiff should be dismissed with prejudice, however certain claims survive the instant motion. Consequently, the "Motion to Dismiss for Failure to State a Claim in Plaintiff's Third Amended Complaint" [Doc. 27] is GRANTED IN PART AND DENIED IN PART, as follows.

I. Standard of Review

Pursuant to 28 U.S.C. § 636(b)(1), "[a] judge of the court shall make a *de novo* determination of those portions of the [magistrate judge's] report [and recommendation] or specified proposed

[1] The defendants state in their objection that they have been incorrectly named as "Stryker Orthopaedics."

findings or recommendations to which objection is made." Section 636(b)(1) further states "[a] judge of the court may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge. The judge may also receive further evidence or recommit the matter to the magistrate judge with instructions."

Pursuant to the foregoing, this Court has made a *de novo* review of the record in this matter as to all objections filed, has considered the arguments and jurisprudence supporting each side, and agrees with the recommendations of the magistrate judge in their entirety for the following reasons.

II. Analysis[2]

Stryker first contends the entirety of the plaintiff's complaint should be dismissed because the plaintiff has not alleged sufficient facts to show the device in question – the ShapeMatch Cutting Guide used in the plaintiff's knee replacement surgery – was actually used during the plaintiff's surgery. The magistrate judge heard evidence on this issue and concluded because neither party can definitively show whether the device was used at the time of the plaintiff's surgery, for purposes of the instant motion, the plaintiff's claims should not be dismissed on this ground, as the plaintiff's medical records will ultimately definitively answer the question. Stryker objects to the foregoing finding. The magistrate judge further recommends the plaintiff's claims of defective composition and breach of warranty be dismissed in their entirety, and the plaintiff's failure to warn claim be dismissed in part, to which Stryker has no objection. Finally, the magistrate judge recommends the plaintiff's defective design claim should not be dismissed, to which Stryker objects.

First, with respect to the issue of product identification, under Rule 12(b)(6) and pursuant to *Twombly*, to survive a motion to dismiss, a complaint must contain factual allegations which are

[2] A factual summary of the case is set forth in the magistrate judge's Report and Recommendation.

"enough to raise a right to relief above the speculative level, *on the assumption that all the allegations in the complaint are true*." 127 S.Ct. at 1965. Here, the magistrate judge noted the factual dispute between the parties as to the precise identification of the device used in the plaintiff's surgery and the lack of sufficient factual information to make a definitive finding as to whether the device in question was the ShapeMatch Cutting Guide. Notwithstanding the parties' dispute, the plaintiff's allegations in the complaint must be taken as true. *See, e.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true). Indeed, the defendants have been unable to come forward with definitive evidence showing the device used in the plaintiff's surgery was NOT the ShapeMatch Cutting Guide. Therefore, the magistrate judge's recommendation that this portion of the pending motion to dismiss should be denied is proper. If it is shown during discovery that the ShapeMatch Cutting Guide was *not* used in the plaintiff's knee replacement surgery, the proper dispositive motion may be filed.

Second, with respect to the plaintiff's claim of defective product design, the magistrate judge concluded as follows:

> In this case, Ms. Corley does not expressly allege that there was an alternative design for the ShapeMatch Cutting Guide that could have prevented her damage. However, she does allege that this product was recalled because of a software defect that resulted in cutting ranges that were wider than they should have been. She also alleges that there was a second software defect that also resulted in cutting parameters not matching the cutting guides. (Rec. Doc. 25 at 4). The undersigned interprets these allegations to mean that an alternative software program, i.e., one without the alleged software defects, existed that would have prevented her alleged damages and could have been used by the defendants. Since Ms. Corley alleges that the ShapeMatch Cutting Guide was a single-use product manufactured from patient specific 3D imaging derived from MRI or CT scans using proprietary 3D imaging software to develop a pre-operative surgical plan for each patient, the undersigned considers the software used in creating each cutting guide to be a necessary part of

> the cutting guide. Accordingly, the undersigned finds that the plaintiff has sufficiently alleged that the cutting guide used during Ms. Corley's surgery was unreasonably dangerous in design due to the alleged software defects. The undersigned recommends that, with regard to the claim asserted under this section of the LPLA, the motion to dismiss should be denied.[3]

The defendants argue plaintiff has failed to argue how or why the design of the ShapeMatch Cutting Guide itself was defective, and further argue the magistrate judge erred in interpreting the plaintiff's allegations that there were defects in the software program to mean that an alternative software program existed at the time the product left the manufacturer's control, because the plaintiff has made no such allegations in her complaint. However, contrary to the defendants' argument, the plaintiff need not *prove* her claim in her complaint; she need only sufficiently *allege* her claim at this stage of the litigation. The plaintiff alleges the following in her complaint:

THE STRYKER SHAPEMATCH CUTTING GUIDE

8. In May, 2011, Defendants received EPA clearance for its ShapeMatch Cutting Guides for use with the company's Triathalon Total Knee System.

9. The ShapeMatch Cutting Guides are single use, disposable cutting guides. They are intended to be used as surgical instrumentation to assist in the positioning of total knee replacement (orthoplasty) components in guiding the marking of bone before cutting.

10. According to Defendants the single use ShapeMatch Cutting Guides are designed and manufactured from patient specific 3D imaging data that is derived from MRI or CT scans.

11. ShapeMatch Technology utilizes proprietarty 3D imaging software to develop a customized pre-operative surgical plan for each patient. Upon surgeon review and approval the plan is used to develop cutting guides for the individual patient.

12. In April, 2013, the FDA notified health care professional of a Class 1 recall for the product due to a software defect that results in wider cutting

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[3] *See* Report and Recommendation, Doc. 31, at pp. 9-10.

> ranges. The parameters of the manufactured cutting guides may not meet the surgeon's pre-operative planing parameters entered via the web application. Additionally, Stryker Corporation through their Stryker Orthopaedics division determined that another software defect resulted in the displayed parameters (e.g., depth of resection angle of cut) not matching the cutting guides produced.
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> 13. These defects may result in serious adverse health consequences, including joint instability, fracture, need for revision surgery and chronic pain and limitations in mobility.[4]

This Court agrees with the magistrate judge that the foregoing allegations sufficiently allege a design defect claim. While certain factual information necessary to prove the claim may be forthcoming in discovery – such as when and whether an alternative software program existed at the time the product left the manufacturer's control – it is not necessary for such detailed information to be included in the complaint in order for the complaint to survive the motion to dismiss. All that is necessary at this stage of the litigation is for the plaintiff to plead "enough facts to state a claim for relief that is plausible on its face." *In re Katrina Canal Breaches Litigation*, 495 F.3d 191, 205 (5th Cir. 2007), *quoting Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact). *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This court "must accept all well-pleaded facts as true and view them in the light most favorable to the non-moving party." *In re Southern Scrap Material Co., LLC*, 541 F.3d 584, 587 (5th Cir. 2008). This Court concludes the facts as pled by the plaintiff sufficiently allege a claim for defective design under the LPLA.

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[4] *See* Plaintiff's Third Amended Complaint, Doc. 25, at ¶¶8-13.

III. Conclusion

Considering the foregoing, the "Motion to Dismiss for Failure to State a Claim in Plaintiff's Third Amended Complaint" [Doc. 27] is GRANTED IN PART AND DENIED IN PART. Specifically, this Court concludes the plaintiff has stated an LPLA claim with regard to her claim that the ShapeMatch Cutting Guide was (1) unreasonably dangerous in design and (2) unreasonably dangerous due to inadequate warnings to the extent that no warnings were provided along with the product, all for the reasons set forth by the magistrate judge in his Report and Recommendation, there being no objections to said reasons by any party. Considering the foregoing, defendants' motion to dismiss the foregoing claims is DENIED. However, in all other respects, the plaintiff fails to state cognizable claims under the LPLA, and the plaintiff's remaining claims – including plaintiff's claim of unreasonable danger based upon defective composition; unreasonable danger based upon inadequate warnings; and unreasonable danger based upon failure to comply with express warranties -- are DENIED AND DISMISSED WITH PREJUDICE.

THUS DONE AND SIGNED in Chambers, Lafayette, Louisiana, this 3 day of July, 2014.

REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE